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**510(k) Summary**

[as required by 21 CFR 807.92(c)]

**SheathLess Eaucath Coronary Guide Catheter**

**510(k)** \_\_\_\_\_

**APPLICANT**

Asahi Intecc Co., Ltd.  
1703 Wakita-cho, Moriyama-ku  
Nagoya, Aichi 463-0024  
Japan

Owner/Operator Number: 3003775027

**OFFICIAL  
CORRESPONDENT**

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OCT 24 2013

**TRADE NAME:**

SheathLess Eaucath Coronary Guide Catheter

**COMMON NAME:**

Guide Catheter

**DEVICE**

Class 2 per 21 CFR §870.1250

**CLASSIFICATION:**

**CLASSIFICATION  
NAME:**

Catheter, Percutaneous

**PRODUCT CODE**

DQY

**PREDICATE**

**DEVICES:**

K021256	6F Launcher Guide Catheter (Medtronic Vascular)
K022764	7F Launcher Guide Catheter (Medtronic Vascular)
K023402	8F Launcher Guide Catheter (Medtronic Vascular)
K972484	ACS Viking Catheter (Guidant Corp.)
K091188	ASAHI ZenyteEX Guiding Catheter (ASAHI Intecc Co., Ltd.)
K092372	Heartrail III Guiding Catheter (Terumo Medical Corp.)
K051601	Pinnacle Destination (Terumo Medical Corp.)

**DATE PREPARED:**

July 25, 2013

**INTENDED USE:**

The SheathLess Eaucath Coronary Guide Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced. The guide catheter is intended to be used in the coronary vascular system.

**DESCRIPTION:**

The SheathLess Eaucath Coronary Guide Catheter is intended for use in coronary vascular applications and is designed to provide a pathway through which medical instruments, such as balloon catheters, guide wires or other therapeutic devices may be introduced. This device is not intended for use in the cerebral vasculature.

The SheathLess Eaucath Coronary Guide Catheter consists of a "Catheter" and "Dilator". The catheter consists of a tube, which is to be inserted into vasculature, a proximal hub/connector, and strain relief/protector. This product is being offered in two sizes: 6.5Fr and 7.5Fr.

**COMPARISON TABLE WITH PREDICATE DEVICES:**

Comparisons of the SheathLess Eaucath Coronary Guide Catheter and predicate devices show that the technological characteristics of the SheathLess Eaucath such as intended use, components, design, materials, sterilization method, shelf life and operating principle are similar to the current marketed predicate devices.

**NON CLINICAL TESTING / PERFORMANCE DATA:**

Non clinical laboratory testing was performed on the SheathLess Eaucath Coronary Guide Catheter to determine substantial equivalence. The following testing/assessments were performed:

Performance test/evaluation summary:

- Corrosion resistance
- Force at break
- Liquid leakage under pressure test
- Air leakage into hub assembly during aspiration
- Kinking short term test
- Coating integrity / Particulate Evaluation
- Radiopacity
- Dimensional Verification

Biocompatibility:

- Cytotoxicity
- Intracutaneous / Irritation
- Sensitization
- Systemic Toxicity

- In Vitro Hemolysis
- In Vivo Thromboresistance
- Plasma Recalcification Time Coagulation
- C3a Complement Activation
- SC5b-9 Complement Activation
- Pyrogen

Package integrity:

- Visual inspection
- Seal strength test

Sterilization:

- Ethylene oxide sterilization evaluation
- EO residuals
- Endotoxin

**CONCLUSION:**

The SheathLess Eaucath Coronary Guide Catheter has the same intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended, and is as safe and effective as its predicate.

Therefore, the SheathLess Eaucath Coronary Guide Catheter is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

October 24, 2013

Asahi Intecc Co., Ltd.  
C/O Semih Oktay  
CardioMed LLC  
5523 Research Park Drive, Suite 205  
Baltimore, MD 21228

Re: K132556  
Trade/Device Name: SheathLess Eaucath Coronary Guide Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: August 23, 2013  
Received: August 26, 2013

Dear Semih Oktay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):** K132556

**Device Name:** SheathLess Eaucath Coronary Guide Catheter

**Indications for Use:**

The SheathLess Eaucath Coronary Guide Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced. The guide catheter is intended to be used in the coronary vascular system.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*M. G. Hillebrand*